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09

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/835,082 04/12/01 RATAIN

M ARCD:374US/G

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HM12/1010

EXAMINER

JIANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/835,082	RATAIN ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-99 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

This application is a CIP of Serial No. 09/553,829.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-54 and 74-76 drawn to a method for reducing the toxicity of flavopiridol comprising administering flavopiridol in combination with a second agent effective to reduce excretion of an active flavopiridol species through the bile, classified in class 514, subclass 285 and 410 for example.
- II. Claims 55-67 drawn to a composition and a kit comprising administering flavopiridol in combination with a second agent that increase conjugative enzyme activity, classified in class 536, subclass 285 and 410 for example.
- III. Claims 68-73 drawn to a method for predicting the degree of a flavopiridol drug toxicity in a patient, classified in class 514, subclass 285 and 410 for example.
- IV. Claims 77-84 and 88-97 drawn to a method for evaluating the toxicity of flavopiridol in a patient, classified in class 436, subclass 64 for example.
- V. Claims 85-87 and 98-99 drawn to a method for reducing the toxicity of flavopiridol in a cancer patient comprising a) identifying a polymorphism in a UGT1A9 gene in a sample from the patient, classified class 514, subclass 285 and 410 for example.

Inventions Group II; and I, III-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, for example, mechlorethamine may be used a method for treating small cell lung cancer.

Inventions Group I and III-IV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are separate and distinct each from the other because they have different functions. The invention of Group I functions to reduce the toxicity of flavopiridol. The invention of Group III functions to predict the degree of a flavopiridol drug toxicity in a patient. The invention of Group IV functions to evaluate the toxicity of flavopiridol in a patient. The invention Group V functions to reduce the toxicity of flavopiridol in a cancer patient comprising a) identifying a polymorphism in a UGT1A9 gene in a sample from the patient. Therefore, they have different functions.

Each invention above relates to a separate and distinct area of pharmaceutical technology. The search for all inventions would place an undue burden on the Office in view of the diversity in the field of search for each.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

### ***Election of Species***

This application contains claims directed to the following patentably distinct species of the claimed invention: second agents effective to reduce excretion of an active flavopiridol species through the bile. See, e.g., claim 1.

Applicant is required under 35 U.S.C. 121 to elect a combination of a specified individual flavopiridol and second agent for Group I-II for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Group I-II are generic to a plurality of disclosed patentably distinct species. The claims read on the employment of various compounds with great diversity of chemical structure classified across class 514, the search for all of which presents an undue burden on the Office. It is noted that a reference to one individual agent would not be a reference to another individual agent under 35 U.S.C.103.

Applicant is required under 35 U.S.C. 121 to elect a specific disease or condition to be treated for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Group I and III-V are generic to a plurality of disclosed patentably distinct diseases or conditions. The claims read on a method of treatment without specifying which disease or condition to be treated. It is

noted that a reference to one disease or condition to be treated would not be a reference to another disease or condition to be treated under 35 U.S.C.103.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P Sec. 812.01.

Application/Control Number: 09/835,082  
Art Unit: 1617

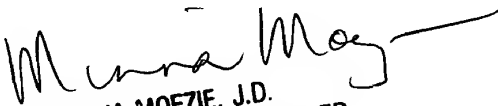
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
October 1, 2001

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
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